

SEP 04 2007

Application No.: 10/039,935

Customer No.: 53,096

Response to First Office Action After RCE, dated June 07, 2007

REMARKS

Claims 56-58, 61-65, 67-76, and 78-81 are pending in the application. Claims 56, 71 and 78 are independent.

Reconsideration and favorable action are respectfully requested.

I. Claim Rejections - 35 USC § 112

1. Claims 56-58, 61-65 and 67-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In particular, "including a chelating agent" (present claims 56 and 71) is a concept that was not present in the specification as originally filed. Therefore it is considered new matter. Applicants are advised that the issue here is not whether particular instances of calcium chelating agent are found, but rather whether the concept of any chelating agent was present in the specification as originally filed. The Examiner contends that support for any chelating agent was not present in the specification as originally filed. The specification as originally filed contains the following disclosures concerning chelating agents:

- (i) "...The matrix comprises a thickening agent, an agent for stabilizing the hydrogen peroxide-containing compound, a pH adjusting agent 25 and a calcium chelating agent." (page 4, lines 23-25);
- (ii) "...a calcium chelating agent is included in the composition to prevent precipitation of calcium ions. (Table 1-4)" (page 6, lines 1-4);

- (iii) "...examples of calcium chelating agents include any of the calcium chelating agents known in the art" (page 6, lines 8-9);
- (iv) "...calcium chelating agents may prevent this precipitation of calcium ions with the associated observed improvement of tooth bleaching effect." (page 6, lines 17-18);
- (v) "...more particularly 8-9.5 that includes a calcium chelating agent" (page 7, line 11).
- (vi) "...positive effect of the calcium chelating agent on tooth bleaching..." (page 14, line 1).

The above disclosures, however, do not provide adequate support for any chelating agent. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention.

*Lockwood v. American Airlines, Inc.*, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

Considering the teachings provided in the specification as originally filed, the Examiner finds that Applicants have failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicants had possession of the concept of a "chelating agent". A chelating agent that has two coordinating atoms is called bidentate; one that has three, tridentate; and so on. EDTA, or ethylenediaminetetraacetate, one of the claimed "chelating agents" is a common hexadentate chelating agent. There is no teaching in the instant specification as to how one would choose a chelating agent, other than the calcium chelating agents set forth as in (i)-(vi) above.

Applicant respectfully traverses the rejection.

While it is true that a calcium chelating agent is fully disclosed, as noted by the Examiner, there is also sufficient support in the disclosure as filed for a chelating agent in general. See page paragraphs [0026], [0029] and [0039] of the published specification US2002/0141951, which correspond to lines 8-14, 8-13 and 1-6 of pages 8, 10 and 14 of the application as filed, respectively. These disclosures of chelating agents are not just specific to calcium chelating agents, but to chelating agents in general. Applicant respectfully submits that the above cited paragraph definitely provides sufficient support for a chelating agent in the claims. Reconsideration is respectfully requested.

2. Claim 81 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding the "mixing baffle" of claim 81, the claim states "The dosage delivery unit of claim 78 wherein the static mixer includes a mixing baffle." It is unclear to the Examiner how the "mixing baffle" differs from the static mixer. Turning to the instant specification on page 7, lines 22-24, it states that the mixing of the two components can be readily achieved using a multi-component tube containing a baffle, otherwise known in the art as a static mixer. The way the claim is stated, one is led to believe that the baffle is a separate component comprised in the static mixer, however the instant specification describes it as one and the same. Clarification is required.

Applicant respectfully submits that there is no ambiguity in the claim as submitted. A static mixer includes many different versions, including a mixing baffle. This is clearly stated in the specification as cited by the Examiner. At the same time, while a mixing baffle can itself be a version of a static mixer, versions of a static mixer

are not mutually exclusive, i.e., they can be combined to make another static mixer. Therefore, a mixing baffle can also be part of a static mixer even if it is also known as a static mixer itself.

Reconsideration is respectfully requested.

## II. Claim Rejections -35 USC § 103

Claims 56-58, 61-65, 67-76 and 78-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christina-Beck et al. U.S. Patent No. 5,766,574.

Christina-Beck et al. teach a dual component whitening dentifrice composition (see abstract). The peroxide is *inter alia* sodium percarbonate (a hydrogen peroxide containing compound) (column 3, lines 11-12) and further comprises thickeners, such as block copolymers having a molecular weight of 4000 (column 3, lines 47-67), water in an amount of from 5 to 30% (column 3, lines 42-46), and chelating agents such as sodium acid pyrophosphate (column 4, lines 1-10). It does not teach a stabilizing agent, however, it is noted that the stabilizing agent instantly claimed in claim 63 is sodium acid pyrophosphate, which is present in the composition of Christina-Beck as a chelating agent. "Products of identical chemical composition (i.e. sodium acid pyrophosphate) can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims (i.e. a stabilizing agent) are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of

monomers and procedures sufficed to support a *prima facie* case of unpatentability of Spada's polymer latexes for lack of novelty.").

The pH of the formulation is in the range of 5 to 8, which overlaps and partially encompasses claims 58 (pH greater than 5.5), claim 67 (pH within a range of between 6 and 10), claim 68 (pH within a range of between 7 and 10) and claim 69 (pH within a range of between 8 and 9.5).

Christina-Beck et al. differs in that it does not teach an alkaline pH-adjusting agent *per se*. However, the pH of the dentifrice partially overlaps and encompasses the pH range of the instant claimed dosage delivery unit as noted above. The criticality of the specific alkaline pH-adjusting agents has not been disclosed. In the absence of any criticality and/or unexpected results of the instantly claimed alkaline pH-adjusting agents of claim 62, the instant invention is considered obvious.

Christina-Beck et al. does not teach the amount of water to be at least 70% water by weight, based on the weight of the mi (claim 61). It teaches water in the peroxide component in an amount between 5 — 30% (column 3, lines 42-46) and in the abrasive component in an amount between 10 and 20% (column 4, lines 40-41) to total about 15 to 50% water. As anyone of ordinary skill in the art will appreciate, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves no more than the application of routine skill in the art of chemical engineering. See, only as exemplary, the dicta of *In re Aller* 105 USPQ 233. Similarly, the determination of optimal values within a disclosed range is generally considered obvious. See, only as exemplary, the dicta of *In re Boesch* 205 USPQ 215. For these and other self-evident reasons, it would have been obvious to add water greater than 70%.

Regarding the static mixer of the device, Christina-Beck et al. differs in that there is not a mixing baffle/static mixer disclosed, however, the dual component composition is "maintained separate from the other until dispensed and combined for application to teeth requiring whitening" (see abstract). The mixing of the two components takes place on the toothbrush. Although there is not a mixing baffle, it would have been made obvious to one of ordinary skill in the art at the time it was made to have used a dispenser with a mixing baffle motivated by a desire to keep incompatible components separate until use and simultaneously mix and deliver the two components in substantially equal amounts immediately prior to use.

Applicant respectfully traverses the rejection.

Christina-Beck et al. U.S. Patent No. 5,766,574 discloses "a dual component dental whitening composition for home use which when applied to teeth contains a combination of a peroxide compound and an abrasive material normally incompatible with the peroxide compound whereby both heightened whitening and stain removal from teeth is attained." See col. 2, lines 30-3. It then goes on to disclose that the invention "is based upon the discovery that when a separately maintained peroxide dentifrice component and an abrasive containing dentifrice component which abrasive is normally incompatible with peroxide compounds are combined for the first time and applied to the surface of the teeth, an enhanced whitening effect is obtained, when the teeth are brushed, as a result of the combined presence of the peroxide and abrasive ingredients. In one embodiment of the invention, a dual component dental whitening composition is provided which is comprised of separate urea peroxide and calcined alumina containing dentifrice components which are housed in a container wherein the components are maintained separate from each other and are not combined and

admixed until simultaneous application to teeth is to be performed by the user as by brushing. Unexpectedly when the separately maintained dentifrice components are contacted with each other immediately prior to application to teeth, the ingredients contained in these components do not appreciably immediately react to decompose the urea peroxide and the combined dentifrice component composition will contain sufficient urea peroxide, in unreacted form, for a time sufficient, e.g., 1 to 10 minutes, to allow the peroxide, in its undecomposed, unreacted efficacious form, to be applied to the teeth simultaneously with a dentifrice component containing a normally incompatible abrasive material." (Emphasis added). See col. 2, lines 37-62. Therefore, not only does Christina-Beck et al's patent not disclose the use of a mixer, but it specifically teaches away from a mixer, as the components are maintained separate from each other and are not combined and admixed until simultaneous application to teeth is to be performed by the user as by brushing", as noted above and a direct quote from the disclosure of Christina-Beck et al's patent. As admitted by the Examiner, Christina-Beck et al. differ in that there is not a mixing baffle/static mixer disclosed. When a patent's disclosure specifically teaches away from the present invention of claim 56, 71 and 78, the Examiner has no sound basis to reject claims 56, 71 and 78 on obviousness, as the only teaching or motivation to have used a dispenser with a static mixer is provided by the Applicant's invention. That is hind sight construction, which is not permitted. Therefore, claims 56, 71 and 78 are patentable under 35 U.S.C. 103(a) over Christina-Beck et al. U.S. Patent No. 5,766,574.

Claims 57-58, 61-65, 67-70, 72-76 and 79-81 are dependent from claims 56, 71 and 78 and are also rejected under 35 U.S.C. 103(a) as being unpatentable over Christina-Beck et al. U.S. Patent No. 5,766,574. While Applicants do not acquiesce with the particular rejections to these dependent claims, it is believed that this rejection is moot

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in view of the remarks made in connection with independent claims 56 and 71 above. The dependent claims include all of the limitation of the base claims and any intervening claims, and recite additional features which further distinguish them from the cited references. Therefore, dependent claims 57-58, 61-65, 67-70, and 72-76 are also in condition for allowance.

Applicants respectfully request that the rejection of claims 56-58, 61-65, and 67-77 under 35 U.S.C. §103(a) as being unpatentable over Christina-Beck et al. U.S. Patent No. 5,766,574 be withdrawn. Reconsideration is respectfully requested.

### III. CONCLUSION

The applicant believes that this Amendment addresses all of the points raised in the Office Action, and requests reconsideration and allowance of the present application, with pending claims 56-58, 61-65, 67-76, and 78-81.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact the undersigned at 310-845-8501.

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Respectfully submitted,

  
Nancy N. Quan

Reg. 36, 248  
BriteSmile Professional, LLC  
8550 Higuera Street  
Culver City, California 90232  
Direct Line: 310-845-8501  
Facsimile: 310-845-8619  
NancyQ@DiscusDental.com